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GUIDELINES AND INSTRUCTIONS FOR APPLICANTS INTERESTED IN ACCESSING AND UTILIZING THE ALLIANCE CLINICAL AND IMAGING DATA RESOURCE

Overview of Repository Data:

The International Progressive MS Alliance (Alliance) funded a project known as EPITOME, “Enhancing Power of Intervention Trials Through Optimized MRI Endpoints: Identifying a biomarker of disability progression for use in clinical trials”. An important aim of the EPITOME Project was to federate existing, large datasets containing both magnetic resonance imaging (MRI) and clinical follow-up of people living with multiple sclerosis (MS), information that can be used to better understand the progression of clinical disability in such individuals.

Thus far (i.e., as of April 2026), the EPITOME Project has aggregated and anonymized the demographic, clinical, and neuroimaging data of 16 Phase-III Clinical Trials that examined the effects of various treatments on the progression of clinical disability in people with MS. The EPITOME Project’s data repository currently contains anonymized data from ~15,000 individual Subjects studied as part of the

16 Clinical Trials (including clinical data from ~223,000 Visits and neuroimaging data from another ~57,000 Visits).

The Alliance, including Industry partners who have shared data with EPITOME, wishes to provide access to much of this aggregated placebo data with qualified investigators (some data is not available due to data sharing restrictions). **Instructions on how to request access to the data are provided in this document.**

Information regarding the Clinical Trials included is presented below, and the Scientific Data included in the Data Repository is detailed in Appendices A and B.

Please note the National MS Society is the “lead agency” of the International Progressive MS Alliance and all applications and award agreements will be administered by the National MS Society on behalf of the Alliance. McGill University houses the EPITOME project and associated data.

Available Data:

Anonymized conventional **MRI scans** (T1-weighted [pre and post Gadolinium], T2-weighted, PD-weighted, FLAIR, MPRAGE or 3D FLASH as available) are available in NIfTI file format with additional metadata contained in paired .JSON files. MRI data are organized into tar files compressed with bzip, labeled by Subject and Timepoint:

- Data for a single subject visit is organized in a single .tbz file (bzip-compressed tar file) *labeled as CIDR-Subject-ID_Visit.tbz*.
- To ensure confidentiality and data integrity, all associated information (such as trial, trial arm) is contained in the clinical .csv file.

Data released to a specific investigator will be contained in one .zip file for download. In addition to MRI data, anonymized clinical data will be provided in a .csv file along with a data dictionary.

Data will be accessible through an sFTP server housed at McGill University and approved applicants will be provided with access credentials. Data must be downloaded once access is approved; ***neither McGill University nor the Alliance will provide a digital infrastructure or environment for applicant use or data analysis.***

Limitations:

Privacy concerns and restrictions imposed by third-party funders, partners, and data use agreements limit the use of these data to approved projects and **forbid secondary distribution**. All data recipients must sign an agreement acknowledging these restrictions prior to review of an application for access to the data.

How to request data:

Requests for data will be administered through an application process overseen by Governance and Data Access committees of the International Progressive MS Alliance. All applications must be submitted via the online portal at <https://nmss.fluxx.io>.

A data access review committee will review applications and assess alignment to ensure projects are in scope with the objectives of the repository and within the limits of the data sharing agreements. A research proposal for the use of repository data will be considered in scope if: 1) it shows sound scientific rationale, 2) it does not include any confidential information and 3) the outcome of the research proposal will NOT be used for commercial purposes. Projects that will be considered in scope include:

- “Natural history” disease modelling based on placebo arms
- Demographic, clinical imaging, and fluid biomarkers and their relationships with outcomes, including clinical and imaging
- Simulation studies (e.g. Digital placebo twins)
- Generation of new outcome measures

Projects that are out of scope for the use of this data include:

- Comparative effectiveness of drugs in full population, subgroups or individual patients (including by simulation or digital methods)
- Non-MS-related projects
- Projects for profit or commercialization*

*Exceptions may be considered with prior authorization and will require additional information, review and signed agreements. For those wishing to pursue commercial purposes, a separate request must be submitted to the Alliance and will be handled separately from this application process. For additional information, please email Doug Landsman (Douglas.Landsman@nmss.org).

Currently, approved applications will have access to placebo datasets. Companies that have shared data with this initiative will be entitled to all of their own data plus data from the placebo arms of trials sponsored by other companies.

The Data Access review committee anticipates accepting and reviewing applications at least twice per year, and this schedule may be adjusted according to the number of applications received.

Data Access Fee

A one-time fee (per project) is required to access this data for investigators working at academic institutions. Industry members, including SME organizations, will pay for access over a three-year contract period allowing for use on multiple projects. If you are applying from a low- or middle-income country (all countries with a low, lower middle or upper middle income [as defined by the World Bank](#)), this fee will be waived. Fees will only be collected if access is approved. There is no fee for the application.

The fee structure is as follows:

Tier	IPMSA (Alliance) Member	Contributing members to CIDR	Company size	Access fee (EUR)		
				Year 1	Year 2	Year 3
1	YES	YES	N/A	(providing support for database)		
2a	YES	NO	Not SME*	100,000€	80,000€	80,000€
2b	YES	NO	SME*	20,000€	16,000€	16,000€
3	N/A – Academic institution	Not applicable	Not applicable – Academic institutions**	3,000€		
4a	NO	NO	Not SME*	125,000€	100,000€	100,000€
4b	NO	NO	SME*	25,000€	20,000€	20,000€

*SME: Small or Medium-size Enterprise as [defined here](#); ** Academic institutions are defined as organizations dedicated to education and research, which grant academic degrees.

The Clinical Trials that compose the Data:

This table includes (i) ID numbers and links to the description of these Trials on ClinicalTrials.gov, as well as (ii) PubMed ID numbers and links to the PubMed pages describing the original publications associated with these Trials. The Clinical Trials are grouped by the MS groups that were studied. Additional data from existing Clinical Trials and from additional Clinical Trials will be added to the EPITOME Project's data repository as they become available. We anticipate this data will be listed in the Malestrom MetaData Catalogues in the near future.

Clinical Trial	MS Subgroup	Sponsor	ClinicalTrials.gov ID and Link	PubMed ID and Link
ADVANCE -> ATTAIN	RRMS	Biogen	NCT00906399	24794721 ; 30181778
CARE-MS I	RRMS	Genzyme, a Sanofi Company	NCT00530348	23122652
CARE-MS II	RRMS	Genzyme, a Sanofi Company	NCT00548405	23122650
CONFIRM -> ENDORSE	RRMS	Biogen	NCT00451451 ; NCT00835770	22992072 ; 27207449
DEFINE -> ENDORSE	RRMS	Biogen	NCT00420212 ; NCT00835770	22992073 ; 27207449
OPERA1	RRMS	Hoffmann-La Roche	NCT01247324	28002679
OPERA2	RRMS	Hoffmann-La Roche	NCT01412333	28002679
ASCEND-1 -> ASCEND-2		Biogen	NCT01416181	29545067
EXPAND	SPMS	Novartis Pharmaceuticals	NCT01665144	29576505
MAESTRO-03	SPMS	BioMS Technology Corp.	NCT00468611	no publication
INFORMS	PPMS	Novartis Pharmaceuticals	NCT00731692	26827074
OLYMPUS	PPMS	Genentech, Inc.	NCT00087529	19847908
ORATORIO	PPMS	Hoffmann-La Roche	NCT01194570	28002688
SPI2	PPMS, SPMS	MedDay Pharmaceuticals SA	NCT02936037	33222767

Clinical Trial Designs:

As shown below these included Clinical Trials that studied subjects with (i) Relapsing Remitting MS (RRMS), (ii) Secondary Progressive MS (SPMS), or (iii) Primary Progressive MS (PPMS) at the onset of the Trial; and they examined the effectiveness of various **Study Drugs** versus either an (i) Active Control [*i.e.*, standard doses glatiramer acetate (GA) or interferon beta β -1a (INF β -1a)], (ii) a Placebo Control, or (iii) both. The Clinical Trials are grouped by the MS Subgroups studied.

Clinical Trial	MS Subgroup	Sponsor	Study Design (Ratio for Initial Treatment Assignments [Initial Treatments] ->[Subsequent Treatments])
ADVANCE -> ATTAIN	RRMS	Biogen	1:1:1 [Peg-IFN-2wks : Peg-IFN-4wks : Placebo] -> [Peg-IFN-2wks : Peg-IFN-4wks]
CARE-MS I	RRMS	Genzyme, a Sanofi Company	2:1 [Alemtuzumab-12-mg-IV-QD : IFN β -1a]
CARE-MS II	RRMS	Genzyme, a Sanofi Company	2:2:1 [Alemtuzumab-12-mg-IV-QD : Alemtuzumab-24-mg-IV-QD : IFN β -1a]
CONFIRM -> ENDORSE	RRMS	Biogen	1:1:1:1 [BG12-240-mg-BID : BG12-240-mg-TID : GA : Placebo] -> [BG12-240-mg-BID : BG12-240-mg-TID]
DEFINE -> ENDORSE	RRMS	Biogen	1:1:1 [BG12-240-mg-BID : BG12-240-mg-TID : Placebo] -> [BG12-240-mg-BID : BG12-240-mg-TID]
OPERA1	RRMS	Hoffmann-La Roche	1:1 [Ocrelizumab-600-mg : IFN β -1a]
OPERA2	RRMS	Hoffmann-La Roche	1:1 [Ocrelizumab-600-mg : IFN β -1a]
ASCEND-1 -> ASCEND-2		Biogen	1:1 [Natalizumab : Placebo] -> [Natalizumab]
EXPAND	SPMS	Novartis Pharmaceuticals	2:1 [Siponimod : Placebo]
MAESTRO-03	SPMS	BioMS Technology Corp.	1:1 [MBP8298 : Placebo]
INFORMS	PPMS	Novartis Pharmaceuticals	1:1 [Fingolimod : Placebo]
OLYMPUS	PPMS	Genentech, Inc.	2:1 [Rituximab : Placebo]
ORATORIO	PPMS	Hoffmann-La Roche	2:1 [Ocrelizumab-600-mg : Placebo]
SPI2	PPMS, SPMS	MedDay Pharmaceuticals SA	1:1 [Biotin : Placebo]

Data storage, access, associated timelines and reuse considerations:

Repository where data will be archived:

Data will be accessible through an sFTP server at McGill. Approved applicants will be provided with access credentials and will be governed by a Data Access Agreement.

When and how long the scientific data will be made available:

Data will be available following approval of an application for access and for the duration of an executed data access agreement.

Factors affecting subsequent access, distribution, or reuse of scientific data:

Privacy concerns and restrictions imposed by third-party funders, partners, and data use agreements limit the use of these data to approved projects and forbid secondary distribution.

Protections for privacy, rights, and confidentiality of human research participants:

Tabular data will be anonymized as indicated above. MRI data will be anonymized by including only anonymized metadata and defacing scans.

Oversight of Data Management and Sharing:

Data access will be controlled by a Governance Committee and Data Access Committee of the International Progressive MS Alliance.

APPENDIX A: Description of Scientific Data:

Clinical-Trial Visits:

The EPITOME Project’s data repository currently includes Clinical-Trial data from **13,074 individual Subjects**, and as shown in the table below, these include data from a total of *(i)* **199,108 CLINICAL Visits** (during which the Subjects’ Clinical data were obtained; these, and associated Demographic data, will be made available in Tabular form as described in **Section 2.a**), *(ii)* and **51,978 MRI Visits** (during which the Subjects’ MRI data were obtained; these MRI data are described in **Section 2.b**); and *(iii)* **6,229 ATTACK Visits** (which are Unscheduled Visits following an MS attack).

As also shown in the table below, these various Visits took place *(i)* prior to the Subjects’ randomization into their trial, *(ii)* during the Core Phase of the trial (*i.e.*, while they were on the Study Drug or in one of the Control conditions, with data that would have been included in the original publications), or *(iii)* during an Extension Phase of the trial, with data which would not have been included in the original publications). The Clinical Trials are grouped by the MS Subgroups studied.

Clinical Trial	Number of Visits Included in Dataset (by Phase of Study and Type of Visit)											
	Total Number of Visits			Visits Prior to Randomization			Visits During Core Study			Visits During Extension Study		
	CLINICAL Visits	MRI Visits	ATTACK Visits	CLINICAL Visits	MRI Visits	ATTACK Visits	CLINICAL Visits	MRI Visits	ATTACK Visits	CLINICAL Visits	MRI Visits	ATTACK Visits
ADVANCE -> ATTAIN	26,719	8,719	1,238	4,750	1,524		11,955	3,198	782	10,011	3,993	456
CARE-MS I	6,538	1,685	241	4,270	556		10,884	1,550	636	10,328	2,104	722
CARE-MS II	9,278	2,380	517	4,181	420		8,766	1,270	551	9,388	1,761	638
CONFIRM -> ENDORSE	25,482	4,210	1,358	831	819		7,779	2,271	376	2,315	254	77
DEFINE -> ENDORSE	22,346	3,452	1,189	867	839	1	7,803	2,239	369	2,139	191	66
OPERA1	10,925	3,344	453	438	438		4,829	1,532	19			
OPERA2	10,809	3,269	436	678	1,178		7,838	1,694	72	4,513	420	26
ASCEND-1 -> ASCEND-2	28,169	5,017	196	595	267		5,943	1,418	241			
EXPAND	17,130	7,157	277	903	785	3	20,313	3,184	193	6,953	1,048	
MAESTRO-03	3,152	1,909		525	535		2,627	1,374				
INFORMS	13,931	3,419	73	3,364	1,525		13,766	5,632	277			
OLYMPUS	5,267	1,970	19	1,918	826		12,013	2,593	73			
ORATORIO	13,029	3,292	98	644	612		5,689	1,543	134			
SPI2	6,333	2,155	134	382	436		2,843	663	24			
Overall	199,108	51,978	6,229	24,346	10,760	4	123,048	30,161	3,747	45,647	9,771	1,985

Clinical-Trial Subjects:

The table below summarizes data from the **13,074 individual Subjects** that are currently included in the EPITOME project's data repository. These data include (i) the number of Subjects from each of the Clinical Trials (as well as the percentage of these that were female); (ii) the mean (and range) of these individuals' (a) ages, (b) number of MS attacks in the year prior to randomization, (c) scores on the Expanded Disability Status Scale (EDSS) at the time of randomization, and (d) mean times to complete the Timed 25-Foot Walk (T25FW) at the time of randomization; as well as (iii) the number of Subjects in each of the MS subgroups at the time of randomization; and (iv) the number of individuals assigned to each of the Treatment Arms at the time of randomization. The Clinical Trials are grouped by the MS Subgroups studied. A small percentage of data will be withheld to prevent attempts at reproduction of the original analysis of trial data. These will be selected based on the availability of MRI scans, issues with data completeness, and random selection.

Clinical Trial	Clinical Trial Subjects' Demographic and Clinical Information at Time of Randomization										Treatment Assignment at Time of Initial Randomization		
	Total Subjects Studied		Age, Attacks in Previous Year, EDSS Scores, and Timed 25-Foot Walk Mean Times				MS Subgroup Studied (Total Number per Subgroup)			(Total Number per Assignment)			
	# Subjects (% Female)		Age (in yrs) mean (range)	Attacks mean (range)	EDSS Score mean (range)	T25FW (in sec) mean (range)	RMSS	SPMS	PPMS	Study Drug	Active Control	Placebo Control	
ADVANCE -> ATTAIN	1,512	70.8%	36.5 (18-61)	1.5 (1-5)	2.5 (0.0-5.5)	7.7 (3-96)	1,512			1,012		500	
CARE-MS I	581	64.7%	33.0 (18-53)	1.8 (0-5)	2.0 (0.0-4.0)	5.4 (2-51)	581			386	195		
CARE-MS II	840	66.9%	35.1 (18-55)	1.6 (0-6)	2.7 (0.0-6.5)	6.6 (2-91)	840			609	231		
CONFIRM -> ENDORSE	1,429	70.1%	36.8 (18-56)	1.4 (0-8)	2.6 (0.0-5.5)	7.1 (2-122)	1,429			707	359	363	
DEFINE -> ENDORSE	1,234	73.6%	38.0 (18-56)	1.3 (0-6)	2.4 (0.0-6.0)	7.8 (3-152)	1,234			826		408	
OPERA1	820	66.0%	37.0 (18-55)	1.3 (0-5)	2.8 (0.0-6.0)	7.6 (3-95)	820			410	410		
OPERA2	835	66.0%	37.2 (18-55)	1.3 (0-6)	2.8 (0.0-6.0)	7.8 (3-180)	835			417	418		
ASCEND-1 -> ASCEND-2	889	61.9%	46.7 (20-58)	0.2 (0-3)	5.6 (3.0-6.5)	13.4 (3-53)		889		440		449	
EXPAND	1,645	60.0%	48.0 (21-63)	0.3 (0-4)	5.4 (2.5-7.0)	16.3 (3-503)		1,645		1,099		546	
MAESTRO-03	506	68.2%	52.2 (26-66)		5.6 (2.4-7.0)			506		252		254	
INFORMS	970	48.8%	48.3 (24-67)		4.5 (2.5-7.0)	8.9 (3-149)			970	483		487	
OLYMPUS	439	50.3%	49.9 (18-66)		4.8 (2.0-6.8)	12.5 (3-145)			439	292		147	
ORATORIO	732	49.3%	44.5 (18-65)		4.7 (2.5-6.8)	14.0 (3-180)			732	488		244	
SPI2	642	53.7%	52.7 (26-65)		5.5 (3.0-6.5)	12.5 (4-44)		414	228	326		316	
Overall	13,074	69.7%	42.6 (18-67)	1.2 (0-8)	3.9 (0.0-7.0)	9.8 (2-503)	7,251	3,454	2,369	7,747	1,613	3,714	

Tabular Data:

For each individual Subject in the EPITOME data repository, anonymized data will be made available in a comma-separated value (**CSV**) file containing the following data. Please note that not all Trials collected all of the following data, and not all individual Subjects within a Trial had all of the data available at each Visit. Note also that additional data may be added to those described below as it becomes available. These data are described briefly below, and are detailed in **Appendix B (Section 0)**

Trial-related data:

These include, for each Individual Subject:

- The name of the Trial that they were studied in (as shown in the tables in **Section 1.a**)
- The anonymized Site at which they were studied (anonymized as a 16-character-long ID made up of combinations of upper- and lower-case ascii letters and ascii digits).
- Their anonymized Trial-ID Number (anonymized as a 16-character-long ID made up of combinations of upper- and lower-case ascii letters and ascii digits).
- The Trial Arm that they were originally randomized into (*e.g.*, Study Drug, Active Control, Placebo Control).
- The name of the Treatment that they received (*i*) during the Core Phase of the Trial; and, if available, (*ii*) during the Extension Phase of the Trial
- The route, dosage, schedule, and duration of their Treatment
- Their anonymized REFERENCE date (*i.e.*, the date of their randomization into their Trial); [REFERENCE dates were anonymized by shifting the actual randomization date to July-1st of the year that individual Subject was randomized].
- Their anonymized Age at their anonymized REFERENCE date, which were anonymized by binning into one of five bins:

15 to <20
20 to <25
25 to <35
35 to <50
50 to <75

- When available, the days that they (*i*) started and (*i*) ended the Extension Phase of being studied (both expressed relative to each Subjects' anonymized REFERENCE date).

Subject-related data:

These include, for each individual Subject:

- Their Sex (*i.e.*, male, female, or other), and their Hand Dominance (*i.e.*, ambidextrous, left, or right).
- Their anonymized Body Mass Index (**BMI**) [these were anonymized by binning into one of the six bins of Nutritional Status according to the World Health Organization (**WHO**)]:

"Underweight"	BMI <18.5
"Normal Weight"	BMI 18.5–24.9

“Pre-Obesity”	BMI 25.0–29.9
“Obesity Class I”	BMI 30.0–34.9
“Obesity Class II”	BMI 35.0–39.9
“Obesity Class III”	BMI >40

- Their comorbidity status at the time of their randomization with regards to (i) Smoking, (ii) Hypertension, (iii) Diabetes Mellitus, (iv) Hyperlipidaemia, (v) Coronary Heart Disease, and (vi) Peripheral Vascular Disease.
- Their anonymized Race (anonymized by binning into “Caucasian” or “other”).
- Their anonymized Region, which were anonymized by binning into one of the six WHO Regions:

“AFR”	African Region
“AMR”	Region of the Americas
“EMR”	Eastern Mediterranean Region
“EUR”	European Region
“SEAR”	South-East Asian Region
“WPR”	Western Pacific Region

MS-related data

These include, for each individual Subject:

- Their MS Subgroup they belonged to at time of Randomization (*i.e.*, RRMS, SPMS, or PPMS).
- Their MS-Treatment status and duration at time of Randomization
- The days of their (i) MS Symptom-Onset, (ii) MS Diagnosis, and (iii) last MS Attack (all expressed relative to each Subject’s anonymized REFERENCE date).
- The number of MS attacks they experienced during (i) the 1 year prior to, (ii) the 2 years prior to, (iii) the 3 years prior to, and (iv) in total prior to being randomized into their Trial.

Visit-related data

These include, for each of an individual Subject’s Visits:

- The sequential number of each their Visits during the Trial (starting at 1), as well the day of each Visit expressed relative to their anonymized REFERENCE date.
- The Trial Phase for that Visit (*i.e.*, PRIOR, REFERENCE, CORE, EXTENSION).
- The Type of that Visit (*i.e.*, REFERENCE, CLINICAL, MRI, ATTACK)
- Descriptive Labels describing that Visit (both the one used for the original Trial, as well as a standardized one used across all Trials in the EPITOME Repository).
- The type of Treatment administered for that Visit.

- A Log number to, if necessary, link to an extended comment regarding that Visit in the corresponding line in the associated “LOG” file.

ATTACK-Visit-related data

These include, for each of an individual Subject’s ATTACK Visits (*i.e.*, Unscheduled Visits following an MS attack):

- The Treatment administered in response to the Attack.
- The (*i*) Start Day and (*ii*) End Day of the Attack (both expressed relative to each Subject’s anonymized REFERENCE date).
- A score for (*i*) the Severity of the Attack, and for (*ii*) the degree of Recovery from the Attack (both as supplied in the original Trial data).

CLINICAL-Visit-related data

These include, for each of an individual Subject’s CLINICAL Visits (*i.e.*, Scheduled Visits for Clinical Testing):

- The Type of CLINICAL Visit (*i.e.*, SCREENING, BASELINE, CLINICAL, UNSCHEDULED)
- Performance on Hauser’s Ambulation Index, and the Day it was administered (expressed relative to each Subject’s anonymized REFERENCE date).
- Performance on the Expanded Disability Status Score (**EDSS**), and the Day it was administered (expressed relative to each Subject’s anonymized REFERENCE date).
- Performance on each of the Functional Systems (**FS**) included in the EDSS
- Performance on the Timed 25-Foot Walk (**T25FW**), and the Day it was administered (expressed relative to each Subject’s anonymized REFERENCE date).
- Performance on the 9-Hole Peg Test (**9HPT**), and the Day it was administered (expressed relative to each Subject’s anonymized REFERENCE date).
- Performance on the Paced Auditory Serial Addition Task (**PASAT**), and the Day it was administered (expressed relative to each Subject’s anonymized REFERENCE date).
- Performance on the Symbol Digit Modalities Test (**SDMT**), and the Day it was administered (expressed relative to each Subject’s anonymized REFERENCE date).
- Performance on the Binocular Low-Contrast Visual Acuity Test (**BLCVA**), and the Day it was administered (expressed relative to each Subject’s anonymized REFERENCE date).
- Serum concentration of Neurofilament Light Chains (**NfL**), and the Day it was tested (expressed relative to each Subject’s anonymized REFERENCE date).

MRI-Visit-related data

These include, for each of an individual Subject’s MRI Visits (*i.e.*, Scheduled Visits for MRI scanning):

- The Day of each MRI Visit expressed relative to their anonymized REFERENCE date.
- The Field Strength of the MRI Scanner used.
- The interval between each MRI Visit and its associated CLINICAL Visit.

MRI data:

Anonymized conventional MRI scans (T1 (pre and post Gadolinium), T2, PD, FLAIR, MPAGE or 3D FLASH as available) will be provided in NIfTI and .JSON pairs.

MRI data will be organized in the following manner:

- Data for a single Subject visit will be organized in a single *visit directory*.
- These visit directories will be stored in a *subject directory* with a label for the Subject and visit.
- These *subject directories* will be stored in a *trial arm directory* with a label for the trial arm.
- Trial arm directories will be archived using tar for sharing data.
- DICOM to NIfTI converter used

APPENDIX B: Data Dictionary for Tabular Data CSV Files

Column	Field Name	Description of Data	Data Type	Examples of String Data
1	TRIAL_ Name	name of Clinical Trial that Subject was studied for	string	"ADVANCE"
2	SUBJECT_ Trial_Site_ID - ANONYM	Subject's anonymized trial-site ID (16-char ascii upper- and lower-case letters and/or ascii digits)	string	"9AGnEzQDb8r HYimj"
3	SUBJECT_ Number_ ANONYM	anonymized Subject unique ID (16-char ascii upper- and lower-case letters and/or ascii digits)	string	"2uXoRGsNv67X FjLI"
4	SUBJECT_ Trial_Arm	trial arm that Subject was randomized to	string	
5	SUBJECT_ Treatment_N ame	generic drug name for MS treatment during trial CORE phase	string	
6	SUBJECT_ Extension_Tr eatment_ Name	generic drug name for MS treatment during trial EXTENSION phase	string	
7	SUBJECT_ Treatment_R oute	route of MS drug administered	string	
8	SUBJECT_ Treatment_D osage	dosage of MS drug administered	string	
9	SUBJECT_ Treatment_S chedule	regimen of MS drug administered	string	
10	SUBJECT_ Treatment_D uration	treatment duration during a trial for example	float	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
11	SUBJECT_Study_Extension_Start_Day	day of entering trial EXTENSION phase (relative to REFERENCE date)	integer	
12	SUBJECT_Study_Extension_End_Day	day of ending trial EXTENSION phase (relative to REFERENCE date)	integer	
13	SUBJECT_Sex	Subject's sex	string	"female", "male", "other"
14	SUBJECT_Dominant_Hand	Subject's dominant hand	string	"right", "left", "ambidextrous"
15	SUBJECT_BMI_ANONYM	body mass index (BMI) using data range buckets (6 WHO bins)	string	"underweight", "normal weight", "pre-obesity", "obesity class I", "obesity class II", "obesity class III"
16	SUBJECT_Smoking	history of smoking	string	"current", "former", "never", "passive", "na"
17	SUBJECT_Hypertension	comorbidity of hypertension	string	"no", "yes"
18	SUBJECT_Diabetes_Mellitus	comorbidity of diabetes mellitus	string	"no", "yes"
19	SUBJECT_Hyperlipidaemia	comorbidity of hyperlipidaemia	string	"no", "yes"
20	SUBJECT_	comorbidity of coronary heart disease	string	"no", "yes"

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
	Coronary_Heart_Disease			
21	SUBJECT_Peripheral_Vascular_Disease	comorbidity of peripheral vascular disease	string	"no", "yes"
22	SUBJECT_Race_ANONYM	Subject's race (2 data bins)	string	"caucasian", "other"
23	SUBJECT_Region_ANONYM	country/region that the Subject was studied in (6 WHO world region bins)	string	"AFR", "AMR", "EMR", "EUR", "SEAR", "WPR"
24	SUBJECT_Screening_Visit_MS_Type	Subject's MS subtype at screening	string	"NC", "PMS", "PPMS", "RRMS", "SPMS"
25	SUBJECT_Prior_MS_Treatment_Status	history of prior MS treatment	string	"no", "yes"
26	SUBJECT_Prior_MS_Treatment_Duration	duration of prior MS treatment	float	
27	SUBJECT_MS_Symptom_Onset_Day	day of MS symptom onset (relative to REFERENCE date)	integer	
28	SUBJECT_MS_Diagnosis_Day	day of MS diagnosis (relative to REFERENCE date)	integer	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
29	SUBJECT_ MS_Last_Attack_ Day	day of last MS attack (relative to REFERENCE date)	integer	
30	SUBJECT_ MS_Attacks_Prior_ Randomization_ 1y	time-binned number of attacks for one year prior to randomization	integer	
31	SUBJECT_MS_ Attacks_Prior_Randomization_ _2y	time-binned number of attacks for two years prior to randomization	integer	
32	SUBJECT_ MS_Attacks_Prior_Randomization_ 3y	time-binned number of attacks for three years prior to randomization	integer	
33	SUBJECT_ MS_Attacks_Prior_Randomization_ All	time-binned number of attacks for all years prior to randomization	integer	
34	VISIT_ Number	line number in Subject's CSV data	integer	
35	VISIT_ Day	day of Visit (relative to REFERENCE date)	integer	
36	VISIT_ Trial_Phase	trial phase at Visit	string	"PRIOR", "REFERENCE", "CORE", "EXTENSION"

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
37	VISIT_ Type	type of Visit	string	"REFERENCE", "CLINICAL", "ATTACK", "MRI", "WITHDRAWAL"
38	VISIT_ Label_Origin al	original Clinical-Trial label for Subject's Visit	string	"WEEK 48"
39	VISIT_ Label	standardized label for Subject's Visit	string	"ADVANCE_CLI NICAL_EXTENSI ON_WEEK_48"
40	VISIT_ Study_Treat ment	study treatment(s) that Subject is being administered at a Visit	string	"none", "placebo", "tx0", "tx1", "tx2", ...
41	ATTACK_ Study_ Treatment	drug treatment given to Subject for attack (cortico- steroids in particular)	string	
42	ATTACK_ Start_Day	start day of attack symptomatology (relative to REFERENCE date)	integer	
43	ATTACK_ End_Day	approximate day of stabilization after attack (relative to REFERENCE date)	integer	
44	ATTACK_ Severity	score for attack severity (as per sponsor)	string	
45	ATTACK_ Recovery	score for level of attack recovery (as per sponsor)	string	
46	CLINICAL_ Visit_Type	CLINICAL Visit type	string	"SCREENING", "BASELINE", "CLINICAL", "UNSCHEDULED "

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
47	CLINICAL_ Ambulation_ Day	day of ambulation-testing (relative to REFERENCE date)	integer	
48	CLINICAL_ Ambulation_ Description	Subject's ambulation in words	string	
49	CLINICAL_ Ambulation_ Score	<p>Subject's ambulation index score</p> <p>Ambulation Index Score: Rating scale developed by Hauser et al (1983) to assess mobility by evaluating the time and degree of assistance required to walk 25 feet. Scores range from 0 (asymptomatic and fully active) to 10 (bedridden). The subject is asked to walk a marked 25-foot course as quickly and safely as possible. The examiner records the time and type of assistance (e.g., cane, walker, crutches) needed.</p> <p>0: Unrestricted</p> <p>1: Fully ambulatory</p> <p>2: >= 300 meters, but < 500 meters, without help or assistance (EDSS 4.5 or 5.0)</p> <p>3: >= 200 meters, but < 300 meters, without help or assistance (EDSS 5.0)</p>	integer	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
		<p>4: \geq 100 meters, but $<$ 200 meters, without help or assistance (EDSS 5.5)</p> <p>5: Walking range $<$ 100 meters without assistance (EDSS 6.0)</p> <p>6: Unilateral assistance, \geq 50 meters (EDSS 6.0)</p> <p>7: Bilateral assistance, \geq 120 meters (EDSS 6.0)</p> <p>8: Unilateral assistance, $<$ 50 meters (EDSS 6.5)</p> <p>9: Bilateral assistance, \geq 5 meters, but $<$ 120 meters (EDSS 6.5)</p> <p>10: Uses wheelchair without help; unable to walk 5 meters even with aid, essentially restricted to wheelchair; wheels self and transfers alone; up and about in wheelchair some 12 hours a day (EDSS 7.0)</p> <p>11: Uses wheelchair with help; unable to take more than a few steps; restricted to wheelchair; may need some help in transferring and in wheeling self (EDSS 7.5)</p> <p>12: Essentially restricted to bed or chair or perambulated in wheelchair, but out of bed</p>		

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
		most of day; retains many self-care functions; generally has effective use of arms (EDSS 8.0)		
51	CLINICAL_ Ambulation_ Distance_ Unilateral_Assistance_ Category	ambulation distance with unilateral assistance (category)	string	
52	CLINICAL_ Ambulation_ Distance_ Bilateral_Assistance_ Category	ambulation distance with bilateral assistance (category)	string	
53	CLINICAL_ Ambulation_ Distance_ No_Assistance_ m	ambulation distance without rest or assistance (meters)	string	
54	CLINICAL_ Ambulation_ Distance_ Unilateral_Assistance_ M	ambulation distance with unilateral assistance (meters)	string	
55	CLINICAL_ Ambulation_ Distance_ Bilateral_Assistance_ M	ambulation distance with bilateral assistance (meters)	string	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
56	CLINICAL_ED SS_ Day	day of Expanded Disability Status Score (EDSS) testing (relative to REFERENCE date)	integer	
57	CLINICAL_ED SS_ Score_ Observed	EDSS score (based on observed FS scores) 0: normal neurological exam (all FS grade 0) 1.0: no disability, minimal signs in one FS (one FS grade 1) 1.5: no disability, minimal signs in more than one FS (more than one FS grade 1) 2.0: minimal disability in one FS (one FS grade 2, others 0 or 1) 2.5: minimal disability in two FS (two FS grade 2, others 0 or 1) 3.0: moderate disability in one FS (one FS grade 3, others 0 or 1) though fully ambulatory; or mild disability in three or four FS (three /four FS grade 2, others 0 or 1) though fully ambulatory 3.5: fully ambulatory but with moderate disability in one FS (one FS grade 3) and mild disability in one or two FS (one/two FS grade 2) and others 0 or 1; or	float	

Column	Field Name	Description of Data	Data Type	Examples of String Data
		<p>fully ambulatory with two FS grade 3 (others 0 or 1);or fully ambulatory with five FS grade 2 (others 0 or 1)</p> <p>4.0: ambulatory without aid or rest for >= 500 meters; up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1) or combinations of lesser grades exceeding limits of previous steps</p> <p>4.5: ambulatory without aid or rest for >= 300 meters; up and about much of the day, characterised by relatively severe disability usually consisting of one FS grade 4 and combination of lesser grades exceeding limits of previous steps</p> <p>5.0: ambulatory without aid or rest for >= 200 meters (usual FS equivalents include at least one FS grade 5, or combinations of lesser grades usually exceeding specifications for step 4.5)</p> <p>5.5: ambulatory without aid or rest for >= 100 meters</p> <p>6.0: unilateral assistance (cane or crutch) required to walk at least 100 meters</p>		

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
		<p>with or without resting (see chapter 8, Ambulation)</p> <p>6.5: constant bilateral assistance (canes or crutches) required to walk at least 20 meters without resting (see chapter 8, Ambulation)</p> <p>7.0: unable to walk 5 meters even with aid, essentially restricted to wheelchair; wheels self and transfers alone; up and about in wheelchair some 12 hours a day</p> <p>7.5: unable to take more than a few steps; restricted to wheelchair; may need some help in transferring and in wheeling self</p> <p>8.0: essentially restricted to bed or chair or perambulated in wheelchair, but out of bed most of day; retains many self-care functions; generally has effective use of arms</p> <p>8.5: essentially restricted to bed much of the day; has some effective use of arm(s); retains some self-care functions</p> <p>9.0: helpless bed patient; can communicate and eat</p>		

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
		<p>9.5: totally helpless bed patient; unable to communicate effectively or eat/swallow</p> <p>10: death due to MS</p>		
58	CLINICAL_EDSS_Score_Converted	<p>neurostatus-converted EDSS score</p> <p>[based on converted visual Functional System (FS) score and converted bowel/bladders FS score]</p>	float	
59	CLINICAL_FS_S_Day	day of Functional System (FS) testing (relative to REFERENCE date)	integer	
60	CLINICAL_FS_S_Bowel_Bladder	bladder/bowel FS score (observed)	integer	
61	CLINICAL_FS_S_Bowel_Bladder_Converted	<p>bladder/bowel FS score (converted)</p> <p>When determining the Neurostatus-Converted EDSS score, the Bladder/Bowel FS score is converted to a lower score as follows: 6=5; 5=4; 4=3; 3=3; 2=2; 1=1.</p>	integer	
62	CLINICAL_FS_S_Brainstem	brainstem FS score	integer	
63	CLINICAL_FS_S_Cerebellar	cerebellar FS score	integer	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
64	CLINICAL_FS S_ Cerebellar_ with_Interfer ence	Cerebellar testing was interfered with by Pyramidal weakness (BMRC grade 3 or worse in limb strength) or sensory deficits	string	"no", "yes"
65	CLINICAL_FS S_ Cerebral_Me ntal	cerebral/mental FS score	integer	
66	CLINICAL_FS S_ Cerebral_Me ntal_ Subtype	Cerebral/Mental Functional Scale Score (Subtype of 1) 1A: mood alteration (depression and/or euphoria) alone; does not affect EDSS step 1B: mild fatigue; signs only decrease in mentation	string	"1A", "1B"
67	CLINICAL_FS S_ Pyramidal	pyramidal FS score	integer	
68	CLINICAL_FS S_ Sensory	sensory FSS	integer	
69	CLINICAL_FS S_ Sensory_ Subtype	2A: mild decrease in touch or pain or position sense or moderate decrease in vibration in one or two limbs; 2B: mild vibration or figure-writing or temperature decrease alone in more than two limbs 3A: moderate decrease in touch or pain or position	string	"2A", "2B", "3A", "3B", "4A", "4B", "5A"

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
		<p>sense or marked reduction of vibration in one or two limbs</p> <p>3B: mild decrease in touch or pain or moderate decrease in all proprioceptive tests in more than two limbs</p> <p>4A: marked decrease in touch or pain in one or two limbs; and/or moderate decrease in touch or pain</p> <p>4B: marked reduction of proprioception in more than two limbs</p> <p>5A: loss (essentially) of sensation in one or two limbs</p>		
70	CLINICAL_FS S_ Visual	visual functional scale score (observed)	integer	
71	CLINICAL_FS S_ Visual_ Converted	<p>visual functional scale score (converted)</p> <p>When determining the Neurostatus-Converted EDSS score, the Visual FS score is converted to a lower score as follows: 6=4; 5=3; 4=3; 3=2; 2=2; 1=1</p>	integer	
72	CLINICAL_T2 5FW_Day	day of Timed 25-Foot Walk (T25FW) testing (relative to REFERENCE date)	integer	
73	CLINICAL_T2 5FW_	did the Subject wear an ankle-foot orthosis during the T25FW?	string	"no", "yes"

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
	Ankle_Foot_Orthosis			
74	CLINICAL_T2 5FW_ Assistive_De vice	did the Subject use an assistive device during the T25FW?	string	"no", "yes"
75	CLINICAL_T2 5FW_ Trial_1_ sec	T25FW: trial 1 (seconds)	float	
76	CLINICAL_T2 5FW_ Trial_2_ sec	T25FW: trial 2 (seconds)	float	
77	CLINICAL_T2 5FW_ Mean_ sec	T25FW: mean of trials 1 and 2 (seconds)	float	
78	CLINICAL_9H PT_Day	day of 9-Hole Peg Test (9HPT) testing (relative to REFERENCE date)	integer	
79	CLINICAL_9H PT_ DomHand_ Trial_1_ sec	9HPT: dominant hand: trial 1 (seconds)	float	
80	CLINICAL_9H PT_ DomHand_ Trial_2_ sec	9HPT: dominant hand: trial 2 (seconds)	float	
81	CLINICAL_9H PT_ DomHand_	9HPT: dominant hand: mean of trials 1 and 2 (seconds)	float	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
	Mean_ sec			
82	CLINICAL_9H PT_ NonDomHan d_ Trial_1_ sec	9HPT: nondominant hand: trial 1 (seconds)	float	
83	CLINICAL_9H PT_ NonDomHan d_ Trial_2_ sec	9HPT: nondominant hand: trial 2 (seconds)	float	
84	CLINICAL_9H PT_ NonDomHan d_ Mean_ sec	9HPT: nondominant hand: mean of trials 1 and 2 (seconds)	float	
85	CLINICAL_PA SAT Day	day of Paced Auditory Serial Addition Task (PASAT) testing (relative to REFERENCE date)	integer	
86	CLINICAL_PA SAT _Form	PASAT: test form administered (A or B)	string	"A", "B"
87	CLINICAL_PA SAT 3_Sec_Total	PASAT: total score with 3- second interval (on 60)	integer	
88	CLINICAL_PA SAT 2_Sec_Total	PASAT: total score with 2- second interval (on 60)	integer	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
89	CLINICAL_SD MT Day	day of Symbol Digit Modalities Test (SDMT) testing (relative to REFERENCE date)	integer	
90	CLINICAL_SD MT Form	SDMT: form tested on (A, B, C, or D)	string	"A", "B", "C", "D"
91	CLINICAL_SD MT_ Oral_ Score	SDMT: score on oral testing (on 60)	integer	
92	CLINICAL_SD MT_ Written_ Score	SDMT: score on written testing (on 60)	integer	
93	CLINICAL_SD MT_ Unknown_ Modality_ Score	SDMT: score on unknown modality testing (on 60)	integer	
94	CLINICAL_BL CVA_ Day	day of Binocular Low-Contrast Visual Acuity (BLCVA) testing (relative to REFERENCE date)	integer	
95	CLINICAL_BL CVA_ 100_Total	BLCVA: total correct on 100% chart (on 120)	integer	
96	CLINICAL_BL CVA_ 2p5_Total	BLCVA: total correct on 2.5% chart (on 60)	integer	
97	CLINICAL_BL CVA_ 1p25_Total	BLCVA: total correct on 1.25% chart (on 60)	integer	

<u>Column</u>	<u>Field Name</u>	<u>Description of Data</u>	<u>Data Type</u>	<u>Examples of String Data</u>
98	CLINICAL_NfL_Day	day of Neurofilament Light Chain (NfL) testing (relative to REFERENCE date)	integer	
99	CLINICAL_NfL_Serum	concentration of NfL chain in serum	float	
100	MRI_Visit_Day	day of MRI Visit	integer	
101	MRI_Magnetic_Field_Strength	MRI scanner's magnetic field strength	float	
102	I2C_Discrepancy_Days	Interval in days between the MRI_Visit_Day and its associated CLINICAL_Visit_Day	integer	
103	I2C_CLIN_Visit_Day	index pointing from MRI Visit to corresponding CLINICAL Visit (if available)	integer	
104	I2C_CLIN_Visit_Index	index pointing from MRI Visit to corresponding CLINICAL Visit (if available)	string	"ADVANCE_CLINICAL_VISIT_6"
105	REFERENCE_Date_Year	date of REFERENCE Visit (in general the randomization date) time-shifted to July 1st of that YEAR	date	
106	REFERENCE_Age_yrs_ANONYM	age in range buckets (10 data bins)	string	"0-20", "20-25", "25-30", "30-35", "35-40", "40-45", "45-50", "50-55", "55-65", "65+", ""
107	LOG_Number	number to link CLIN.CSV LOG entry with corresponding line in associated LOG file	integer	

APPENDIX C: Terms & Conditions

General Terms and Conditions of Data Access:

1. Your payment must be made by ACH, wire transfer, or credit card payment before any data will be released. See “Fee Payment Information” below for details.
2. The Alliance reserves the right to revoke this award at any time.
3. Privacy concerns and restrictions imposed by third-party funders, partners, and data use agreements limit the use of these data to approved projects and **forbid secondary distribution**. Data shall be used only for the purposes for which Access Rights to it have been granted.
4. Data shall be owned by the Contributing Member sharing such Data. Subject to approval, each Contributing Member grants the Recipient a limited right to use its Data solely for the direct performance of the approved Research Proposal. All rights and title in and to any and all pre-existing inventions, discoveries, data, chemical entities, methods, compounds and materials developed or controlled by the Contributing Member prior to the Effective Date or during the Term, but not as a result of, in connection with, or otherwise related to the Research Proposal, whether or not patentable, shall reside with the owner thereof and, except as otherwise set forth herein, such ownership and rights thereto shall not be affected by the Research Proposal or a Party’s performance of its obligations hereunder.
5. Results obtained using Data shall be owned by the Recipient who created those Results, provided that where the Data is related to a product or compound owned by a Contributing Member, the Contributing Member is hereby granted an irrevocable, perpetual, non-exclusive, transferrable, royalty-free, worldwide, license under its rights in all new intellectual property for Contributing Member to use, practice, modify, enhance, sublicense or otherwise exploit the product-related Results intellectual property, for any and all purposes, including development of new therapies and the recruitment of the right patients.
 - All Results should be published or, if not published, shall be shared with the Alliance, who will then share with all data contributors, subject to the Contributing Member Confidentiality Obligations.
 - During the term, a Party intending to publish their Results or outcome of the Research Proposal using Data shall share the draft of their publication with the Coalition Members for a review at least 30 (thirty) calendar days prior to publication of manuscripts and papers. Conference abstracts may be shared with shorter timelines or after the submission. For clarity, such review is discretionary and not mandatory for the data-contributing Coalition Members.
 - Notwithstanding any other provisions in this Coalition Agreement, no Data and/or Confidential Information may be published without the express prior written consent of the Party that owns the Data and/or Confidential Information. In the case of conference abstracts shared with the Contributing Members after their submission, Coalition members may ask for the withdrawal of such abstract in the event major issues are identified.
 - An objection is justified if:
 - the protection of the objecting Party's Data would be adversely affected; or
 - the objecting Party's legitimate interests in relation to the Results or Data would be significantly harmed. The objection must include a precise request for necessary modifications.
6. In accordance with scientific customs, a Party’s contributions shall be expressly reflected in all written or oral public disclosures concerning Results by acknowledgement of Alliance and applicable Data Owner(s).

7. Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.
8. It is appropriate for you to acknowledge support from the International Progressive MS Alliance.
9. By accessing these data, the recipient agrees to comply with the requirements and fulfill the commitments contained in this agreement.

Terms of Use of the Data

1. Recipient is regularly engaged in conducting laboratory studies and has all the required authorizations to perform any experimental work at the place of investigation that are required for the Research Proposal. In particular, Recipient is entitled under all applicable laws and regulations to perform the Research Proposal using Data.
2. The Data will be used in full compliance with all laws and regulations applicable in the places where the Research Proposal are performed. Recipient's employees working on the Proposal have adequate training and facilities to use Data, and Recipient will directly supervise the Research Proposal.
3. Data will be used solely for performance of the Research Proposal in the facilities of Recipient under suitable containment conditions in accordance with all applicable laws. Data shall not be published or otherwise made available externally.
4. Data will not be analyzed or modified other than necessary for the purpose of the Research Proposal without the prior written consent of the relevant Contributing Member(s).
5. Data will not be transferred or made available to any individual other than those under the supervision and control of Recipient assigned to the performance of the Research Proposal without the prior written consent of the relevant Contributing Member(s), except that Recipient may make the Data available to third party employees, contractors or Contract Research Organizations for the sole purpose of performing the Research, under obligations of confidentiality and non-use not less strict than those of this Agreement.
6. Data are being supplied to Recipient with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, Data Owner does not represent or warrant that the use of Data will not infringe or violate any patent or proprietary rights of third parties.
7. Data are to be used with caution and prudence in any experimental work. Recipient shall bear all risk to it and/or any others resulting, directly or indirectly, from use, application or storage of Data.
8. The Recipient cannot use the Data, or any Results obtained with the use of Data, for commercial purposes. Any exception to this clause shall be agreed to on a case by case basis between the Recipient, the Coordinator and the relevant Contributing Member.

Privacy Information and Restrictions

Each Party acknowledges the importance of the privacy rights of any individuals and commit to comply with all applicable data privacy and personal data protection legislation. In specific, each Party declares and warrants that it:

- (a) Will not attempt to identify and/or single out any data subject from the Data;
- (b) Will not combine the Data with other sources of data or any other data sets/data bases that may lead to the identification of any individual;
- (c) Will not publicly disclose the Data and will adopt all technical and organizational security measures to prevent any intentional or unintentional, unlawful and/or unauthorized access and/or use of the Data;
- (d) Will ensure confidential access management to the Data to associates, employees or representatives on a need-to-know basis and subject to confidentiality obligations;
- (e) Will apply the best industry standards to protect and keep the data safe from any unintended use, including accidental or unlawful use;
- (f) Will immediately notify McGill University and the Alliance about any incident or breach of the Data of which it is aware, including description and nature of the incident/breach, impacted Data (full or partial) and actions taken to remediate the incident/breach and to prevent further disclosure.